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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,170	10/02/2003	Ross J. Hamel	SYNT-0108	6800

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EXAMINER

WERNER, JONATHAN S

ART UNIT	PAPER NUMBER
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3732

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01/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,170

Applicant(s)

HAMEL, ROSS J.

Examiner

Jonathan Werner

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/31/07.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,9-17,19,21,23,25-36,40,41,44-50 and 52-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9-17,19,21,23,25-36,40-41,44-50,52-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-7, 9-10, 14-17, 19, 21, 23, 25-29, and 52-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Wells (US 5,904,650). Wells discloses a surgical retractor (10) comprising a handle (70) having a longitudinal axis with proximal and distal ends (see Figures 1-3); a first coupling mechanism that comprises a knob (40) having a bore (46) with internal threads at each end (i.e. see Figure 3), wherein said coupling mechanism is coupled to the proximal end of the handle (70) via threads (69), and wherein the bore is rotatable about the longitudinal axis of the handle also via threads (69); and a blade member (20) having a proximal end and a distal end (see

Figures 1-3), wherein said blade member comprises a coupling element (threaded region 28, Figure 3) which is configured and dimensioned to be received in the bore of the knob (40) as shown in Figures 2-3. Additionally, Examiner notes that rotation of the knob (40) causes the threaded coupling element (28) to advance into the threaded portion (44) of the bore of knob (Figures 2-3). The threaded coupling element (28) of the blade comprises a shaft as shown in Figures 2-3, and wherein the bore has mating threads for receiving said shaft. Furthermore, the coupling element of the blade has an aperture (through the threaded shaft, Figures 2-3; column 4, lines 50-51) which is capable of passing a surgical tool therethrough. The blade of Wells also has a structure (i.e. 26/29) at the distal end which can be used to stabilize the retractor against bone during an operation. Wells discloses a second coupling mechanism (68) located on the handle, which couples to a coupling member (50) for supporting a surgical instrument such as an endoscope (column 4, lines 6-19). As shown in Figure 2, an endoscope located in a recess of a second member (i.e. receptacle 30) can be positioned to provide a view of the distal end of the retractor blade since said distal end of the blade extends past the distal end of said receptacle. Figures 2-3 further shown that the coupling member is telescopically received in the handle. Additionally, Examiner notes the coupling member can be adapted to clamp a portion of the surgical instrument depending on the corresponding size of the instrument within the recess. Wells discloses that surgical instruments other than endoscopes (such as a blade) can be coupled to the retractor via the first coupling mechanism (column 4, lines 23-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11-13, 31-36, 40-41, 44-47, and 49-50 are rejected under 35 U.S.C.

103(a) as being unpatentable over Wells in view of Greenberg (US 5,558,622). Wells discloses the claimed invention as previously described, with the exception of "C" or "L" hook shapes at the distal end of the blade for stabilization against bone. Greenberg discloses a surgical retractor with both "C" and "L" hook-shaped distal ends of the retractor blade that help stabilize the blade against bone (Fig. 5, #58; Fig. 17, #M, and Fig. 20, #71B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the retractor blade of Wells to a "C" shape or an "L" shape as taught by Greenberg in order to allow for stabilization against bone. Wells also fails to explicitly disclose the steps of creating an appropriate incision in a patient's tissue necessary for the use of a retractor. However, Greenberg discloses a method for treating a bone that includes providing the surgical retractor, making an incision in the soft tissue and elevating the tissue off the bone (Fig. 17, S, SI, OI and M), passing a portion of the blade through the incision and retracting the tissue (Fig. 17, OI), circumventing at least part of the bone with a portion of the blade and stabilizing a portion of the blade on the bone (Fig. 17, #'s 58, 59, and M), and performing a surgical procedure on the bone (Fig. 17, D and P). Therefore, it would have been obvious to

one having ordinary skill in the art at the time of Applicant's invention to make such an incision in the soft tissue in order to provide a working area for insertion of the retractor during a procedure as taught by Greenberg. Additionally, part of the procedure involves using a surgical tool (D) to pass an orthopedic implant (P) through the cavity (SI) and the aperture of the blade (Fig. 17, #60). The surgical instrument can be a drill (and therefore a burr) (Column 6, lines 22-27) inserted through a drill guide or cannula (Column 2, lines 14-19). The implant secured to the bone can be a bone fastener or a screw (Column 6, lines 22-27) and used in an orthognathic procedure to fixate a fracture (Claim 32) on a bone segment (mandible) that comprises a condylar neck and a ramus.

4. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wells in view of Hipps et al. (US 6,228,025). Wells discloses the claimed invention as described in detail above, with the exception of having a second handle transverse to the longitudinal axis. Hipps et al. discloses a surgical retractor with a second handle transverse to the longitudinal axis of the first handle. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the retractor of Wells with a second transverse handle, as taught by Hipps et al., since adding an additional handle will increase the ability to manipulate and more securely grasp the retractor.

5. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wells in view of Greenberg, as applied to claim 44 above, and further in view of Swaniger (US

4,769,011). Wells and Greenberg disclose the claimed methods as described above, with the exception of using a grafting procedure. Swaniger discloses methods for mandibular surgery that are well known in the art including a grafting procedure (Column 1, lines 21-24), using a biocompatible bone filler material (Column 1, lines 30-38), and the use of a syringe to implant the bone filler material (Column 2, lines 10-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform a grafting procedure as taught by Swaniger in order to augment the alveolar ridge.

Response to Arguments

6. Applicant's amendments to the Abstract have been accepted, the objection of which has been withdrawn. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. Regardless, Examiner points out that while an Applicant can act as his or her own lexicographer, the names of certain reference elements described in the prior art are not required to be the same as the corresponding names of reference elements of the present invention in order for said prior art to read on the present invention. For example, even though Wells calls reference element 70 a "tightener," it is clear that this reference is sufficient to act as the presently claimed "handle" of Applicant's invention as described in the rejection above. In this regard, Examiner notes that, as interpreted in the rejection above, the coupling system of Wells comprising knob (40) and bore (46) with internal threads acts in the same manner as that of the present invention, and wherein knob

(40) of Wells is representative of the same basic shape of Applicant's disclosed knob. Additionally, Merriam-Webster dictionary defines a knob as a small rounded handle. In this case, element 40 is a gripable cylindrical member with internal threads that acts like and serves the same purpose as that of Applicant's knob – namely to secure the blade (20) member thereto via the blade member's coupling element (28).

7. Next, in regard to Wells, Applicant remarks that "the receptacle 30 and not the blade 20 has the alleged coupling element." However, Examiner respectfully disagrees with this assertion. Although receptacle (30) does indeed have a coupling element as pointed out by Applicant, blade (20) also has a coupling element (i.e. the threaded region of element 28) as described in the rejection above. This coupling element (28) as shown in Figures 2-3 is configured and dimensioned to be received in the bore (46) of the knob (40) such that rotation of said knob causes the coupling element to advance within the bore (i.e. the threaded portion of coupling element 28 can advance within bore 46 via the internal threads of the bore at end 44).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cary E. O'Connor/
Primary Examiner
Art Unit 3732


Jonathan Werner
Examiner

1/9/08